Docket No. 02N-0278

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE PROPOSED RULE FOR

PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

AS REQUIRED BY

Section 307

of the

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

April 3, 2003

02N-0278

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The American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry, comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs.

Background and Subject of these Comments

The United States Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, and President Bush signed this legislation into law on June 12, 2002. The Act consists of five separate titles. AHPA and its members have significant interest in the interpretation and implementation of certain of the statutory requirements established in Title III of the Act (Protecting Safety and Security of Food and Drug Supply).

The Food and Drug Administration (FDA) published a notice of proposed rulemaking in the Federal Register on February 3, 2003 to implement two Sections of the Bioterrorism Act, and specifically the requirement to provide prior notice to FDA of all shipments of imported food as required under Section 307 of the Act. This notice specified that comments to the proposed rule should be submitted by April 4, 2003.

Most of AHPA's members are companies that either sell bulk herbs or herbal extracts; that manufacture or process herbal ingredients or consumer goods containing herbs, including dietary supplement and food products; or that market consumer goods containing herbs, including dietary supplement and food products. Many of these companies import some or all of the ingredients for these products or in some cases import finished consumer goods and will therefore have an interest in the proposed rule.

AHPA submitted initial comments on August 30, 2002, in response to FDA's express request in correspondence dated July 17, 2002, to identify concerns and provide recommended solutions related to the implementation of Section 307 of the Act.

Comments to proposed rule – overview

AHPA has comments related to a number of specific elements of this proposed rule for prior notice of imported food as required under the Act. However, all of these specific comments are provided with the hope that FDA will reconsider its entire approach to its proposed rule.

The Act establishes a requirement for submission of "a notice" providing the identity of seven specific subjects (listed below in comment #7) related to all imported foods. In the preamble to the proposed rule that is the subject of these comments FDA acknowledged that it already receives most of that required information.

AHPA is concerned that the agency's approach to implementing this Section of the Act by creating an entirely new mechanism as a separate step for every lot of imported goods is inefficient, at best, and will place a burden on all importers that is unnecessary to fulfill the requirements of this Section of the Act. AHPA believes that the agency needs to reconsider its entire approach by proposing, for example, that the forms that are currently used to provide information to the agency about imported food be revised to include all newly required information and that the procedures that are currently used to provide information to the agency about imported food be revised to meet the timelines required by the Act or even more reasonable timelines. AHPA strongly encourages the agency to consider these suggestions and to seriously evaluate them as much more efficient and cost effective means to implement the Act.

In considering these suggestions, AHPA encourages the agency to maximize its cooperation with the United States Customs Service in the Department of Homeland Security. AHPA notes that the Act specifically requires that the Secretary of the Department of Health and Human Services consult with the Secretary of the Treasury as a precondition for implementing this Section of the Act. AHPA is aware that the Homeland Security Act of 2002 was enacted into law on November 25, 2002, that is, subsequent to the enactment of the Bioterrorism Act, and that this later law transferred the United States Customs Service from the Treasury Department to the new Department of Homeland Security, effective March 1, 2003.

Thus, at the time that the Bioterrorism Act was passed the U.S. Customs Service provided a significant import function for the Department of the Treasury. The Service and these import functions have now transferred to the Department of Homeland

Security. AHPA therefore requests that FDA consider all of its obligations under the Bioterrorism Act to consult with the Department of the Treasury to have been extended to the Department of Homeland Security, at least insofar as the functions of the U.S. Customs Service are concerned.

AHPA is aware that the Federal Register notice in which this proposed rule was published was signed by both the Secretary of Health and Human Services and the Acting Secretary of the Treasury. AHPA does not believe, however, that the proposed rule for prior notice of imported food sufficiently addresses the need for FDA and the U.S. Customs Service to coordinate their activities related to food imports. Significant improvements in the cooperation between these agencies are necessary to implement this Section of the Act in a manner that reduces its burden both on importers and on regulators, and AHPA encouraged additional thought to be given to maximizing such cooperation.

Comments to proposed rule – specific comments

AHPA is providing the following comments to specific proposed rules to implement this Section of the Act.

1. §1.276(b): The agency has proposed in §1.276(b)(1) to exempt from prior notice food that is carried by an individual entering the U.S. in that individual's personal baggage for that individual's personal use and has requested comment as to its reasoning in establishing this exemption.

   AHPA agrees that the exemption identified above is appropriate but is concerned that it may be too narrow in that it does not exempt food that is shipped into the U.S. for an individual's personal use. Many foreign firms have developed their U.S. business by making food products available to individual consumers in this country via Internet sites and by mail order. The proposed exemption would not apply to products shipped from such a facility to a customer in the U.S. AHPA believes that the agency should extend the proposed exemption to all food imported for personal use, whether carried in by an individual or shipped to an individual. AHPA requests that FDA comment on this issue, and on how it can modify the proposed rule to accommodate such commerce.

In addition, AHPA believes that food that is imported for the sole purpose of providing samples to buyers or prospective buyers should be clearly identified as having a non-food use and be specifically exempted from prior notice. The proposed definition of "food" states, "With respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required **if the article is being imported for use as a food**" (emphasis added). Samples are essential for trade; are currently exempted from existing U.S. Customs and FDA importation notice requirements, though they are subject to inspection by federal authorities (U.S. Customs and FDA); and are not imported for use as foods. AHPA requests that the agency clearly establish in final rules that food samples are exempt from prior notice requirements under the Act though should continue to be subject to inspection.

2. §1.278(a)-(c): The Act states that an article of food that is imported or offered for import without submission of a prior notice in accordance with specified requirements shall be refused admission into the United States. The consequences of failure to submit adequate prior notice or otherwise failing to comply with this part is described in proposed §1.278.

   This proposed rule implements the Act by requiring that an article of food that is imported or offered for import with no prior notice or inadequate prior notice be refused admission and held at the port of entry unless FDA directs its removal to a secure facility. The proposed rule identifies in §1.278(c) examples of rationales that might support a decision by FDA to remove such food to a secure facility, including a concern with the security of the article of food or space limitations in the port of entry. The proposed rule describes secure facilities to include a Bonded Warehouse, a Container Freight Station, a Centralized Examination Station, or another appropriate secure facility that has been approved for this purpose by FDA.

   AHPA requests that the requirements for establishing the consequences that are the subject of this paragraph more adequately take into account the effect on commerce of this proposed rule, as is required by the Act, and allow as an option for goods that have in any particular failed to comply with prior notice regulations to be "held in facility," that is, to be held intact at the importer's place of business in a designated FDA quarantine location and to be considered undelivered but held for sampling and release.

3. §1.278(e)(1): As stated in the previous comment, the Act subjects any article that fails to comply with prior notice regulations to refusal to importation. A description of steps that must be taken to complete the importation of such food subsequent to its being held at the port of entry or at a secure facility are described in §1.278(e)(1).

   In the preamble to the proposed rule FDA comments on the status of other goods in the same container or truck, and states, "...when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles that have been refused must be dealt with before the rest of the shipment proceeds." FR 68 at 5432. Although FDA's discussion of this matter was specific to non-food items included with food items in a mixed or consolidated shipment, this policy would apparently be equally relevant to the various food items in a mixed or consolidated shipment . AHPA takes this to mean, for example, that if a container holds 100 food items offered for import and the prior notice for any one of those items is noncompliant in any particular, then the agency intends to hold all 100 food items, whether or not the various food items have any commonality of manufacturer, shipper, owner, importer, or consignee.

   AHPA believes that the practice proposed by FDA in its preamble, if accurately represented here, would be unacceptable and would place an unfair burden both on importers of any non-food item and on importers of food items that are in conformity with prior notice regulations. Such nonaffected importers of non-food items and compliant importers of food items must not be penalized for the failure of another importer to comply with their prior notice obligations.

   AHPA requests that FDA reconsider this proposal and instead state its intention to release to the owner or importer all imported non-food items and imported food items that conform to prior notice regulations without reference to the status of other imported food items in a mixed or consolidated shipment.

4. §1.285: The proposed rule would limit persons who are authorized to submit a prior notice of a food import to a domestic purchaser, a domestic importer, or a U.S. domiciled agent acting on behalf of a domestic purchaser or importer. The agency requested comment on whether others should also be authorized to provide prior notice.

AHPA suggests that a U.S. domiciled agent acting on behalf of a foreign seller or exporter should also be authorized to submit such notices. There is nothing in the Act that forbids such person from this authority. Related to concerns articulated in comment #1 above, foreign based companies that sell primarily directly to individuals in the U.S. foods for the individual's own use can not expect these individual customers to be knowledgeable about importation laws. AHPA reiterates its belief that all food imported for personal use should be exempt from prior notice. Absent any assurance at this time that FDA will agree with this belief, however, AHPA is concerned that the additional burden implied by any requirement for an individual to file prior notice for food for their own use will result in a nearly universal discontinuation of such imports.

Even importers who are not individuals, however, such as retail stores or restaurants, should not be expected to be prepared to submit prior notice, and a foreign seller or exporter may be willing to do this as a service on their behalf. AHPA requests that FDA consider this suggestion to allow a U.S. agent for a foreign seller or exporter to assume this role on behalf of such U.S. importers for exporters who wish to provide such service.

In addition, AHPA requests that the agency authorize international agents of a U.S. owner, importer, or consignee to provide prior notice. Again, there is nothing in the Act that forbids such person from this authority. Although there is some precedent in FDA regulations to require a U.S. agent to act on behalf of foreign firms for certain registration purposes, these precedents are not relevant to the action of filing prior notice of import for a U.S. based owner, importer, or consignee. In this instance, FDA will already have access to a U.S. based entity – the owner, importer, or consignee – as these entities will be required to be registered under Section 305 of the Act.

5. §1.286: The Act specifies that the prior notice of import required under this part be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import. The Act states that this period may not exceed five days. Although there is not a similar statutory limit or definition for the latest time at which the required notification must be made, the Act states that this period must be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification. The Act also states that, in determining the specified period of

time required under this part, the Secretary may consider, among other things, the effect on commerce of such period of time and various modes of transportation. Finally, the Act also states that, in the event that final regulations for this requirement have not been made effective by December 12, 2003, then a default period of time that the notice is required to be made in advance of the time of the importation of the article or the offering of the food for import shall be not less than eight hours and not more than five days.

The agency has proposed to establish rules whereby prior notice of an imported food would be required to be submitted to the agency no sooner than 5 days prior to the anticipated date of arrival of the food at the anticipated port of entry, and no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

The agency's proposal for the earliest time at which a prior notice of import can be filed is exactly the time that was identified in the statute, and AHPA has no comment on that detail. The agency's proposal for the latest time at which a prior notice of import can be filed, however, does not adequately take into account the effect on commerce of such period of time and does not adequately consider various modes of transportation, both factors that the agency is required by the Act to consider in establishing a time for filing prior notice. This time is 4 to 28 hours less than the default minimum period envisioned by the Act. AHPA requests that the agency reconsider this proposed minimum time for filing of a prior notice and establish in the final rule this time to be 8 hours, or even as little as 4 hours in advance of importation, to fully address various modes of transportation and the effect on commerce relative to importation by truck or by air.

6. §1.287: The proposed rule would establish a requirement that a prior notice and all other information required for submission under this part be submitted electronically to FDA through FDA's Prior Notice System at a website to be identified in the final rule, except and unless that system is unable to receive prior notices electronically.

AHPA submitted initial comments on August 30, 2002, in response to FDA's express request in correspondence dated July 17, 2002, to identify concerns and provide recommended solutions related to the implementation of Section 307 of the Act. In these initial comments AHPA stated its belief that, although the Act did

not specifically authorize electronic submission of prior notices of imported foods, electronic methods for submitting such notice are essential to minimizing any burden that might be involved in the notification process. AHPA also noted that nothing in the Act prohibits electronic methods for such purpose.

AHPA believes that most of its members would utilize electronic means for filing a prior notice if given that option and any other option. Nevertheless, AHPA is concerned that the inflexibility expressed in the proposed rule in this matter is unnecessary and does not adequately address the needs of firms that do not have ready Internet access. AHPA is aware that the agency has stated in the preamble to this proposed rule that information that is currently required to be submitted to FDA for imports is done so electronically in 98% of the cases. FR 68 at 5432. AHPA is also aware, however, that the agency estimated in the preamble to the proposed rule for facility registration under Section 305 of the Act that only 71% of domestic firms that are small businesses have access to the Internet. FR 68 at 5394. AHPA is therefore concerned that 29% of small businesses that import food might not be able to conform to the proposed rule and that the agency has recently estimated that 89 percent of domestic firms in the dietary supplement industry are small businesses. FR 68 at 12246. AHPA therefore requests that the agency address this issue.

In addition, AHPA notes that the agency has not identified the means by which confirmation will be provided for submission of a prior notice by any means other than electronic means (whether because the FDA system is not able to receive notices electronically or because the agency has agreed that submissions by means other than electronic means might be allowed in other circumstances). AHPA requests that the agency provide information in this regard.

7. §1.288: The Act specifies information that is required to be submitted in a prior notice as follows: (1) the article; (2) the manufacturer of the article; (3) the shipper of the article; (4) the grower of the article (if known within the specified period of time that notice is required to be provided); (5) the country from which the article originates; (6) the country from which the article is shipped; and (7) the anticipated port of entry for the article.

The proposed rule would require that all of the information identified in the Act be submitted in a prior notice and numerous additional pieces of information also

be submitted. The proposed requirement for certain of the information that is identified by the proposed rule but not required by the Act is reasonable. For example, AHPA has no objection to the inclusion of the identifying information included in numerous sections, for example, in proposed §1.288(a) to identify the individual submitting the notice; in proposed §1.288(f) to identify the manufacturer; in proposed §1.288(g) to identify the grower(s) (if known); or in proposed §1.288(i) to identify the shipper. On the other hand, AHPA does not at this time support the inclusion of all of the information identified as required in proposed §1.288. Additional details follow in the next several comments.

An additional overview concern for this entire section, as stated at the outset of these comments, is the agency's proposal to require a separate and redundant filing of numerous information details that the agency has acknowledged that it is already in receipt of for all imports. The agency itself comments on this in the preamble to the proposed rule, as follows:

> *Most of this information is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process, including the entry type; the entry number (both ACS line number and FDA line identifier); the FDA product code; a written description of the product in common business terms; brand name; the quantity; lot numbers; the manufacturer; country of origin; shipper; importer; ultimate consignee; and the carrier (the mode of transportation and the carrier code).* FR 68 at 5435.

The Act establishes a requirement for submission of "a notice" providing the identity of the seven subjects listed above. FDA has acknowledged that it already receives most of that information, and in fact receives all except the identity of the grower(s) and the country from which the article was shipped. In addition, all of this information, except for the identity of the grower(s), is also submitted to U.S. Customs under current Federal law.

AHPA is concerned that the agency's approach to implementing this Section of the Act by creating an entirely new and redundant mechanism as a separate step for every lot of imported goods is inefficient, at best, and will place a burden on all importers that is unnecessary to fulfill the requirements of this Section of the Act. Examples of this kind of redundancy include but are not limited to: proposed §1.288(b) would require identification of entry type as designated by U.S.

Customs Service and proposed §1.288(c) would require a U.S. Customs Service identification number (ACS or other), even though this information is already submitted to FDA.

AHPA believes that the agency needs to reconsider its entire approach by proposing, for example, that the forms that are currently used to provide information to the agency about imported food be revised to include the newly required information (e.g., the grower(s), if known) and that the procedures that are currently used to provide information to the agency about imported food be revised to meet the timelines required by the Act. AHPA strongly encourages the agency to consider these suggestions and seriously evaluate them as much more efficient and cost effective means to implement the Act.

8. §1.288(e)(1)(i): The agency has proposed that the complete FDA product code from FDA's product code builder be included in the identity of the imported article. AHPA strongly opposes this proposed requirement, at least for the goods that are of most importance to AHPA's members, i.e., botanical ingredients and botanical dietary supplements.

   The concern that leads to this opposition is straightforward: FDA's system for assigning product codes to the regulatory class of goods defined as dietary supplements is incomplete and badly organized. This is especially so for that subclass of dietary supplements defined as "herbs and other botanicals" and extracts thereof.

   To begin with, the overall industry classification in which dietary supplements is placed is industry code 54, defined as, "vitamins, minerals, proteins, and unconventional dietary specialties for humans." This is not well defined for purposes of the class of herbal supplements and was discovered for the purpose of preparation for these comments by trial and error, since the goods sold by AHPA's members (i.e., herbs) are not obvious in this definition. The next two categories (Class = "herbal & botanicals," either teas or other than tea; and Subclass = Human food dietary supplement, single or multiple ingredient) are rational enough. These two are not, however, in a rational order from industry's perspective, as industry (and the Federal definition) thinks of herbs and other botanicals as a subclass of dietary supplements. The next criterion, the process

identification code (PIC), is fairly well designed from a dietary supplement perspective as most of the forms in which these products are sold are listed.

It is in the area of the final data, the product, that this system is most problematic for herbal dietary supplements. The available product codes are lacking in sufficient detail to actually identify all of the goods that are sold, such that any attempt to use the product code builder for herbal supplements will almost necessarily lead to confusion. For example, AHPA's *Herbs of Commerce*, 2nd edition[1], lists over 2,000 herbs that might be used as ingredients in supplements; the product code builder lists 116, seemingly derived almost exclusively from lists of plants that the agency has identified as problematic. Of these, at least six are toxic and would constitute adulterants if included in a supplement; four or more are misspelled; and numerous duplicates are listed (e.g., 17 listings for product #75, identified as any one of a number of species of *Cocculus* or of synonyms for that genus, an ingredient that is, at most, rarely observed in commerce). Five of the listed plants are identified only with a Chinese (*pinyin*) name and none include the part of the plant, an integral element in the identification of a botanical ingredient.

Given all of these concerns the agency must accept that this part of the FDA code builder is simply not ready to represent a required piece of information on prior notices of import of herbal dietary ingredients and dietary supplements. The agency would, by requiring "the complete FDA product code," as is envisioned in proposed §1.288(e)(1)(i), essentially assure that most such products would fail to qualify for import. Another option to this approach to failure is to assume that this entire class of goods can fall into the catch-all "not elsewhere classified." Thus, importers of herbal supplements will find themselves engaged in a process of running all of their products through a multi-component classification system to come out with an identity as "miscellaneous."

If, however, the agency insists that this incomplete reference is to be included as essential identifying information for imported articles that are herbal supplements, AHPA requests that the agency rewrite this subparagraph to provide

[1] AHPA provided the agency with "in press" copies of this current edition of *Herbs of Commerce* several months prior to its publication in December 2000 and has since communicated actively with FDA to assist in revising 21 CFR 101.4(h) to accept this document as a replacement for the 1992 edition incorporated there. AHPA would be pleased to discuss presenting the agency with the current edition of this text in an electronic format to assist in updating the product code builder.

some guidance as to how to meet this requirement, by stating, for example, "The complete FDA product code, but in the event that a product is not fully identified in the product code, the product identity may be identified as "not elsewhere classified" in the appropriate subclass, i.e., as product #99 in that subclass."

9. §1.288(g): The Act specifies that the grower of an imported article be identified in a prior notice "if known within the specified period of time that notice is required to be provided" and this paragraph would implement that requirement.

AHPA requests greater clarification of the agency's expectation for identification of the grower or growers and the amount of effort that an importer should expend in identifying growers, especially when, in the case of an imported lot of botanical raw materials, the lot consists of mixed quantities from multiple growers and the importer may or may not purchase the lot from one of the growers. AHPA does not believe that it would be useful to establish any kind of regulatory expectation that the importer of a lot of this nature should be required to identify all growers that have contributed to such a lot, and does not believe that such requirement would be in furtherance of the Act in any meaningful way.

AHPA is aware that the agency has posed questions on how this part of the Act should be implemented, and specifically: whether the agency has any flexibility to exempt or otherwise treat differently so-called processed foods produced with products from one or more grower; and whether the term "grower" includes a harvester or collector of wild products including botanicals.

AHPA believes that the agency does not need to identify "flexibility" to exempt processed foods produced with products from one or more grower, but should rather recognize that there is not a grower of a processed food. Stated another way, processed foods are not grown, they are processed. There is nothing in the act that suggests that a company that is importing chocolate covered almond nougat candies is supposed to be prepared to identify the grower of the almonds and the chocolate and the sugar and the eggs, etc. (or in the herbal product area, that the importer of a tincture of a five herb blend knows the grower or growers of each of those herbs and of the corn from which the alcohol was produced). The agency should refrain from establishing any such requirement.

With regard to whether the term "grower" includes a harvester or collector of wild products including botanicals, AHPA believes that, although harvesters or

collectors of wild botanicals do not grow botanicals and should be differentiated from growers for certain purposes, these can be included in the term "grower" as the term is used in the Act and consistent with the assumed Congressional intention in Section 307 of the Act to identify the direct source of the agricultural raw commodity. AHPA believes, however, that it is an extremely rare occurrence for any single imported lot of a wild botanical raw material to have been collected by a single collector, and in fact believes that the most common practices in consolidating a single lot of wild-harvested botanical raw material involve the product of many dozen or even hundreds of individual collectors. AHPA does not believe, however, that it would be useful to establish any kind of regulatory expectation that the importer of a lot of this nature should be required to identify all of the collectors that have contributed to such a lot, and does not believe that such requirement would be in furtherance of the Act in any meaningful way.

10. §1.288(k)(1)(i): The proposed rule would require that the anticipated border crossing be identified if the anticipated port of entry has more than one border crossing.

    AHPA has no opposition to this requirement but requests that the agency take into account that the border crossing that is anticipated 5 days in advance of arrival can change due to any number of diversions beyond the control of the importer. AHPA specifically requests that the agency examine means by which communication to the agency of any unexpected change in this information can be provided by the entity that is actually knowledgeable about a change in border crossing, for example, by the ocean or air carrier. It is the carrier that is the party with the most accurate information on arrival location and can therefore provide the most efficient communication to FDA on the arrival border crossing.

11. §1.288(k)(1)(ii): The proposed rule would require that the anticipated date of arrival be identified in a prior notice.

    Although the Act does not specifically require that the date of arrival of imported foods be identified in a notice the need for such information is implied by the fact that the statute does require a notice to be filed no earlier than 5 days prior to import. §1.288(k)(1)(ii) requires that the anticipated date of arrival be identified and, though AHPA has no opposition to such requirement the agency should take into account the fact that the date of arrival that is anticipated 5 days

in advance of arrival can change due to any number of diversions beyond the control of the importer. The agency should also recognize and address the fact that the date of "arrival" at a port of entry is not necessarily the same as the date that an import is unloaded at that port.

AHPA again specifically requests that the agency examine means by which communication to the agency of any unexpected change in this information can be provided by the entity that is actually knowledgeable about a change in the date of arrival, for example, by the ocean or air carrier. It is again the carrier that is the party with the most accurate information on arrival times and can therefore provide the most efficient communication to FDA on arrival date.

12. §1.288(k)(1)(iii): The proposed rule would require that the anticipated time of arrival be identified in a prior notice.

As stated above, AHPA has no opposition to a requirement to identify the anticipated date of arrival so long as the agency takes into account that this date might change for any number of reasons. The more precise requirement to identify the anticipated time, however, is problematic, especially as it relates to proposed §§1.294(a)(2) and 1.294(a)(3). These proposed paragraphs would establish a requirement to amend any prior notice that does not arrive within a 4 hour window of time, such timeframe to be anticipated as much as 5 days in advance. The requirement to meet such a narrow timeframe is unrealistic and has no relation to the actual delivery of imports to U.S. ports. AHPA therefore requests that anticipated time of arrival be removed as a requirement in the final rule.

13. §§1.289 through 1.294 inclusive: The Act is silent on the issue of amendments or modifications to a prior notice once it is submitted by a firm in relation to any given article for import. It can be assumed, however, that the Congressional intent in requiring information to be provided in advance of importation was that all information be accurate and presented in a timely manner to enable FDA to inspect imports as necessary.

AHPA believes, however, that the proposed rules in §§1.289, 1.290, 1.291, 1.292, 1.293, and 1.294 are unnecessarily restrictive. For example, there is nothing in the Act that suggests that there must be a strict limitation on the kind of information that will be allowed to be amended after an original submission of prior notice, as is proposed in §1.289. In addition, the proposal at §1.290 to limit

modifications to a single amendment does not adequately take into account the effect of such limitation on commerce as is required by the Act. AHPA recommends that the agency rethink these proposed sections as well as the next proposed sections that are directly related to these (i.e., §§1.291, 1.292 and 1.293) with a goal to maximize accuracy by creating more opportunities, rather than fewer, for a firm to provide accurate and timely information about its imports. In relation to that goal, AHPA requests that the agency remove §1.291 or replace it with a rule that allows any amendments that are necessary to accurately complete a prior notice or that are otherwise required to filed up to the time of import. AHPA also suggests that the agency consider a means by which a "correcting amendment" could be filed at any time after the original submission of a prior notice in the event that any error in the original is identified, rather than relegating such submission to cancellation.

Of particular concern in these sections is the proposed requirement to identify a 4-hour time window for arrival of an import, as is required by §1.294 and as is discussed in the above comment. This proposal has no reference in reality and AHPA reiterates its belief that this section should be withdrawn.

Additional comments

AHPA has significant concern over the absence of any mention of privacy and protection from disclosure of information submitted on a prior notice. AHPA is aware that, although the Act specifies that certain information required to be provided to FDA under the Act, such as certain information included in a firm's registration of its facilities, would not be subject to disclosure under 5 U.S.C. §552, the Act is silent on this issue for information required to be submitted in a prior notice of import under Section 307 of the Act. Nevertheless, AHPA asserts that the Act did not forbid such protection from disclosure of this information; believes that FDA has authority to establish such protection in this rulemaking process; believes that much of the information required to be disclosed to FDA is proprietary to an individual company; and believes that companies would be damaged by ready access to such information by competitors. AHPA therefore requests the agency to use this authority and establish such protection from disclosure under 5 U.S.C. §552.

Another issue of interest and concern to AHPA's members is the statutory implementation date for food facility registration, and specifically that their businesses will suffer through no fault of their own if the agency fails to complete all that is necessary by December. While AHPA assumes that FDA will diligently work to meet this deadline any uncertainty in this matter should be communicated promptly and openly so that the Congress can consider appropriate actions.

AHPA appreciates the opportunity to provide these comments to the proposed rules for registration of food facilities under the Bioterrorism Act and hopes that the agency will treat these comments seriously.

Respectfully submitted,

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